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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/729,460	12/05/2000	Karl Kolter	51007	4443

7590 02/27/2003

Messrs. Keil & Weinkauff
1101 Connecticut Ave., N.W.
Washington, DC 20036

EXAMINER

DEWITTY, ROBERT M

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 02/27/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/729,460

Applicant(s)

KOLTER ET AL.

Examiner

Robert M DeWitty

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-14 are pending in the instant application. Claim 14 is withdrawn from further consideration. Acknowledgement is made of Applicant's response filed 1/28/03.

1. Applicant's election with traverse to the Office Action mailed 1/10/02 is acknowledged. The traversal of the restriction requirement is treated as a request for reconsideration, since the restriction was made final in paper #6.

Applicant argues that the reasons for restriction are improper because they
2. misuse Applicant's process in showing distinctness. The following is a modification of the reasons why inventions I and III are distinct. Inventions I and II are joined. Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by applying the taste-masking coating without compressing the coated medicinal substance.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-6 provide for the use of a film coating, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 1-10, 12 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Kotler et al. (U.S. Pat. No. 6,046,277).

Kotler teaches the use of redispersible polymer powders for coating pharmaceutical or agrochemical use forms. They can be used to control the release of the active ingredient from the use form (col. 1, lines 5-11). The forms contain 10-95% polyvinyl acetate, 0-20% of water-soluble substances, and other additives. Kotler teaches adding hydrophilic auxiliaries, such as hydroxypropylmethylcellulose, amino acids, water-soluble acids, to increase the rate and additionally stabilize the dispersion (col. 3, lines 50-62). The coated forms can be in the form of granules, having a particle size range from 0.1 to 10mm (col. 5, lines 55-56).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kotler (U.S. Pat. No. 6,046,277), further in view of Wheatley (U.S. Pat. No. 4,693,896),

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Shirai et al. (U.S. Pat. No. 5,082,669), Mehta (U.S. Pat. No. 4,800,087), and Lerner et al. (U.S. Pat. No. 5,840,332).

Kotler teaches the use of redispersible polymer powders for coating pharmaceutical or agrochemical use forms. They can be used to control the release of the active ingredient from the use form (col. 1, lines 5-11). The forms contain 10-95% polyvinyl acetate, 0-20% of water-soluble substances, and other additives. Kotler teaches adding hydrophilic auxiliaries, such as hydroxypropylmethylcellulose, amino acids, water-soluble acids, to increase the rate and additionally stabilize the dispersion (col. 3, lines 50-62). The coated forms can be in the form of granules, having a particle size range from 0.1 to 10mm (col. 5, lines 55-56). However, Kotler does not teach the particular active ingredients claimed.

Wheatley teaches a coated aspirin tablet. The aspirin tablet core is coated with a ethylcellulose polymer containing a plasticizer (col. 1, lines 55-57).

Shirai et al. teaches a pharmaceutical preparation comprising a core and a film layer coating the core (Abstract). It is taught that the drugs applicable to the invention can include pyridonecarboxylic acid antibacterial agents (col. 3, lines 13-15).

Mehta teaches a microencapsulating polymer which coats a pharmaceutical core and is capable of taste-masking the active compound (Abstract). The preferred coating composition is a mixture comprised of high and low film forming polymers. The high film-forming polymer can be hydroxypropylmethyl cellulose, hydroxypropyl cellulose, ethylcellulose polyvinyl alcohol, and polyvinyl acetate (col. 4, lines 13-44).

Lerner et al. (U.S. Pat. No. 5,840,332) teaches a gastrointestinal delivery system comprising a drug in combination with a core material, the core being surrounded by a water-insoluble coating material (Abstract). Examples of materials suitable for the coating include Eudragit E, ethylcellulose, shellac, and waxes (col. 9, lines 62-65). Agents that can be used in the core include NSAID drugs such as diclofenac, flurbiprofen, and aspirin (col. 12, lines 40-67).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to coat pharmaceuticals, particular the ones claimed, with the coating of Kolter. Kolter can accurately control the release of the active ingredient.

Response to Arguments

6. Applicant's arguments with respect to claims 7-9 and 11-13 have been considered but are moot in view of the new ground(s) of rejection.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

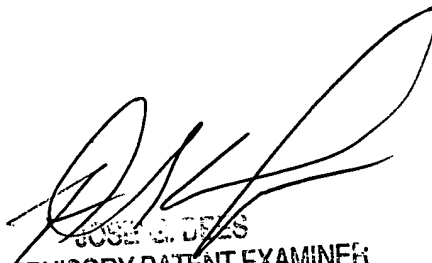
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD
February 26, 2003


JOSE C. DEES
SUPERVISORY PATENT EXAMINER
